

JRC TECHNICAL REPORT

Report on the call for feedback about the scope of the European Quality Assurance scheme for Breast Cancer Services

*European Commission
Initiative on Breast Cancer*

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**Former JRC GH30*

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Table of contents

THE QUALITY ASSURANCE SCHEME DEVELOPMENT GROUP	4
ACKNOWLEDGEMENTS	5
ABSTRACT	6
1. INTRODUCTION	7
2. METHODOLOGY OF THE CALL FOR FEEDBACK	8
2.1 The questionnaire	8
2.2 Data collection and processing	9
3. RESULTS	11
3.1 Information about respondents	11
3.2 Use of the accreditation standards for the European QA scheme	15
3.2.1 Standard ISO 17065:2012	15
3.2.2 Standard ISO 15189:2012	16
3.2.3 Certification scheme requirements (scheme owner requirements)	18
3.3 Services, interventions and diseases covered by the European QA scheme	19
3.3.1 Breast cancer care pathway	20
3.3.2 Subprocesses	21
3.4 The modular approach	24
3.5 The European QA Scheme's contents	28
3.5.1 The Manual of requirements and the indicators	28
3.5.2 Reference documents	30
3.5.3 Quality domains	32
3.6 General comments	34
4. CONCLUSION	35
REFERENCES	36
LIST OF ABBREVIATIONS AND DEFINITIONS	37
LIST OF FIGURES	38
LIST OF TABLES	38
ANNEX I	40
ANNEX II	52

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The ECIBC as a whole is certainly enriched and its implementability enhanced thanks to the feedback received from stakeholders: we wish to thank all respondents for the time, dedication and competence they invested in providing their feedback to the scope of the voluntary European Quality Assurance scheme for Breast Cancer Services (the *European QA scheme*).

Abstract

In 2015 the European Commission Initiative on Breast Cancer (ECIBC) started the development of a voluntary European Quality Assurance scheme for Breast Cancer Services (the *European QA scheme*) through the technical and scientific coordination of the [Directorate-General Joint Research Centre](#) (JRC). To support the JRC in this task, a Quality Assurance Scheme Development Group (QASDG), consisting of independent experts, was established.

The *European QA scheme's* scope (*The Scope*) represented the first output of the development process of the *European QA scheme*. Via a public call, stakeholders and individual citizens were invited to provide their feedback on *The Scope*.

The call was open from 17 February to 9 March 2016 and an on-line questionnaire via the EU Survey platform on the ECIBC web hub was made available. The JRC received a total of 63 valid responses from 15 individuals (24% of total valid responses) and 48 organisations (76%). Individuals and organisations from 23 out of 28 EU Member States (82%) contributed to this exercise.

During a meeting held in Varese (Italy) in March 2016, QASDG discussed how the results of the call for feedback should be reflected in *The Scope*. Decisions taken during that meeting were recorded in the meeting's minutes and *The Scope* was modified accordingly. The final version of *The Scope* was approved by QASDG on 16 May 2016 and was later made publicly available together with this report.

1 Introduction

In 2012, the Directorate-General for Health and Food Safety (DG SANTE) mandated the European Commission's Joint Research Centre (JRC) to coordinate the European Commission Initiative on Breast Cancer (ECIBC). The ECIBC's objectives include the development of the European guidelines for breast cancer screening and diagnosis (henceforth the *European Breast Guidelines*) and the development of a voluntary European Quality Assurance scheme for Breast Cancer Services (henceforth the *European QA scheme*). The *European QA scheme* will define a common set of quality and safety requirements for breast cancer services in Europe. The scheme will cover all relevant processes of breast cancer care. Its requirements will be defined on the basis of evidence-based recommendations arising from high-quality guidelines, best professional practices, and the relevant legislation¹. Once finished, it will be piloted by a restricted list of breast cancer services in Europe selected via a call for expressions of interest and according to a set of characteristics. The piloting is being designed to test the scheme's robustness across a diversity of healthcare settings. More information about the *European QA scheme* and the ECIBC is available at the ECIBC web hub².

To support the European Commission in the development of the *European QA scheme*, a Quality Assurance Scheme Development Group (QASDG) was established in 2015³ following a Call for Expressions of Interest⁴ organised by DG SANTE to support the European Commission, under the JRC's technical and scientific coordination. The European co-operation for Accreditation (EA) supports the *European QA scheme* by framing it within Regulation (EC) No 765/2008 of the European Parliament and of the Council (*European legislation for accreditation*)⁵ in view of its piloting and implementation.

The *European QA scheme's* scope (henceforth *The Scope*) represents QASDG's first output. It is meant to describe:

- the interventions and services that will be covered by the *European QA scheme*;
- the dimensions of quality that will be included;
- how the scheme will be implemented in the European context, and within the *European legislation for accreditation*.

To ensure from the outset of its development that the approach proposed for the *European QA scheme* will be feasible for different health systems, countries and contexts of breast cancer service delivery, stakeholders and individual citizens were invited by a call for feedback to provide their opinions on *The Scope*. This report is about the results of this exercise.

A second call for feedback, on the final version of the scheme's Manual, will be launched before making the scheme publicly applicable once the *European QA scheme's* requirements are available.

1 <http://europa.eu/!JT66Pp>

2 <http://ecibc.jrc.ec.europa.eu/quality-assurance>

3 <http://ecibc.jrc.ec.europa.eu/working-groups>

4 http://ec.europa.eu/health/major_chronic_diseases/diseases/cancer/call_ecibc_en.htm

5 Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93
(<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:en:PDF>)

2 Methodology of the call for feedback

2.1 The questionnaire

The public call for feedback was open from 17 February to 9 March 2016 (3 weeks) by an on-line questionnaire via the EU Survey tool available at the ECIBC web hub⁶.

This on-line consultation was open to all and no pre-registration was required. In order to ensure good coverage through stakeholders' typologies and through countries, several information channels were used: the ECIBC web hub, DG SANTE's newsletter, and European Public Health Association's (EUPHA) newsletter. In addition, all the entities and individuals included in the ECIBC contacts' database received a pre-notification about the call on 5 February (a non-exhaustive list of those contacts is reported in an annual ECIBC publication (1-2)). A reminder e-mail was sent on 2 March 2016 and, finally, an e-mail was sent to thank all participants at the closure of the survey. At the moment of publication of this report and of *The Scope* on the ECIBC web hub, a similar strategy will be put in place to disseminate the information about the availability of these two key ECIBC documents.

Participants were invited to download and print *The Scope* and to read the *First proposal of general requirements of a European QA scheme* provided by EA⁷ before answering the questionnaire. Respondents could indicate how their contribution would appear: under their name (and consent to the publication of all the information in the contribution); anonymously (and consent to the publication of all the information in the contribution, except the name/the name of the organisation); or ask for confidential treatment of the contribution, allowing internal use within the European Commission only.

The online questionnaire was composed of five parts, plus a final free-text box for general comments. The full questionnaire is available in Annex I to this report.

All detailed responses for which the respondent consented to publication, even in anonymised format, are made available on-line in the ECIBC web hub.

- The first part of the questionnaire gathered information about the respondents. They had to identify themselves and indicate whether they were replying as an 'individual' or 'on behalf of an organisation'. The responses from the ECIBC national contacts were considered as 'an organisation', because it was implied that they responded on behalf of the corresponding country.
- The second part contained questions on the *European QA scheme* with respect to the *European legislation for accreditation*. Respondents were asked:
 - whether they agree with the standards selected for accreditation and certification within the *European QA scheme* (i.e. ISO 17065:2012 and ISO 15189:2012);
 - how relevant are the proposed categories for the scheme owner requirements;
 - whether additional scheme owner requirements are needed.

6 <http://ecibc.jrc.ec.europa.eu/-/scope-of-the-european-quality-assurance-scheme-for-breast-cancer-services>

7 <http://europa.eu/!KF79pK>

- The third part related to the activities and conditions covered by the *European QA scheme*. Respondents were asked:
 - whether they agree with the list of services, interventions and diseases proposed;
 - whether the outlined breast cancer screening pathway is applicable in the context of their healthcare system;
 - whether they consider the subprocesses proposed as relevant and whether additional subprocesses are needed.
- The fourth part explored the applicability of the proposed modular approach to the respondent's country healthcare system.
- The fifth part contained questions on the *European QA scheme's* contents. Respondents were asked whether the descriptions of the Manual and of the indicators are clear, whether further typologies of reference documents or further quality domains are needed.

Finally an open-text part at the end of the questionnaire offered respondents the option to add any further comments and to address items not covered by the questionnaire.

A functional mailbox (JRC-ECIBC@ec.europa.eu) managed by the JRC, was available for requests for technical support.

2.2 Data collection and processing

Data were collected by the JRC, including personal data which were treated pursuant to Regulation 45/2001/EC on the protection of individuals with regards to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

Only comments submitted before the deadline and related to the contents of the documents were considered. Comments were excluded if they contained complaints against institutions, personal accusations, irrelevant or offensive statements or material, or content not related to policy aspects relevant for the ECIBC or outside the scope of ECIBC's activity. Comments on *The Scope* received only as free-text e-mails to the functional mailbox were discarded, and hence are not covered by this report and are not considered for the final version of *The Scope*.

A draft feedback report including descriptive tables of responses was shared with the QASDG chair, vice-chair and coordinators of the QASDG subgroups *Organisation, scope and modules, Certification Processes*, and *Quality concepts and Keywords (glossary)*. In particular, this step was meant to screen the suggestions received via the call about modifications, deletions or addition of subprocesses and quality domains, according to their relevance for a full QASDG group discussion.

After the chairs and subgroups had reviewed the tables of responses, all the members of QASDG were involved in discussing and taking decisions on how to incorporate and respond to the feedback received: a set of slides summarising the main results of the call for feedback and highlighting topics for discussion was prepared and presented on 16 March 2016 to the whole of QASDG at a meeting in Varese. Decisions taken during that meeting were recorded in the minutes⁸. The corresponding changes were implemented in the final version of the *The Scope*,

8 <http://europa.eu/!uq37wQ>

which was eventually approved by QASDG on 16 May 2016. The new version including the changes highlighted in red is reported as Annex 2.

In this report, aggregated data are displayed for all the responses received. Comments received from individuals and entities requiring anonymisation are reported without the name of the contributor, whilst comments from individuals and entities asking for confidential treatment of the contribution are not reported at all. The full database of received responses, with the exception of confidential ones, is available through the ECIBC web hub.

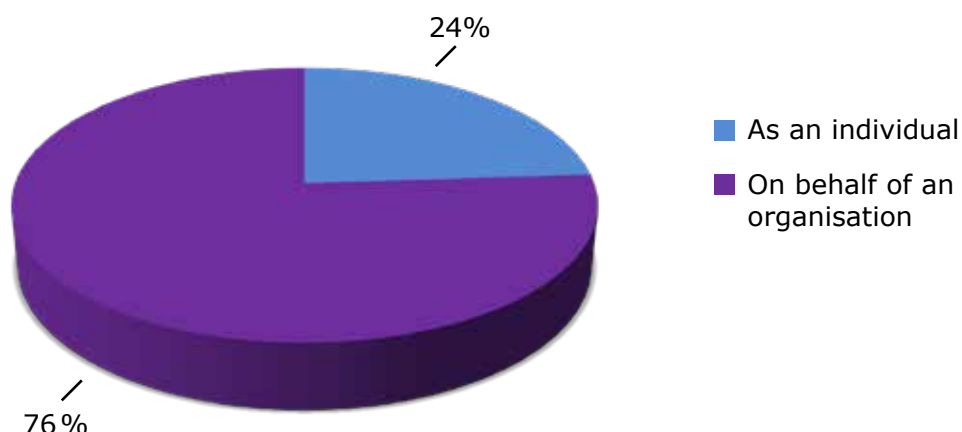
Sensitivity analyses were performed separately, for responses received from individuals and from organisations. As no relevant difference was detected, data from individuals and organisations are reported together.

3. Results

3.1 Information about respondents

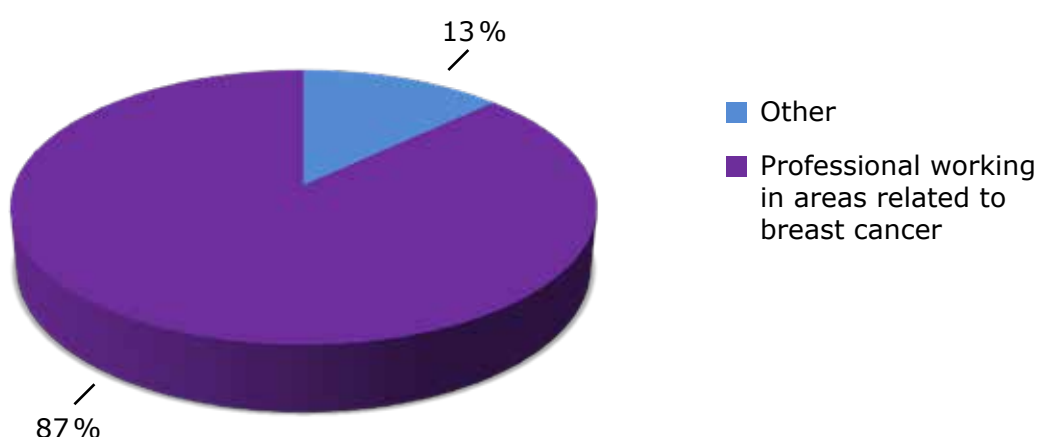
The JRC received a total of 63 valid responses, from 15 individuals (24% of total) and 48 organisations (76%). Please note that affiliation is based on self-identification by respondents and has not been validated.

Figure 1. Distribution of survey responses to the public call for feedback (n=63)



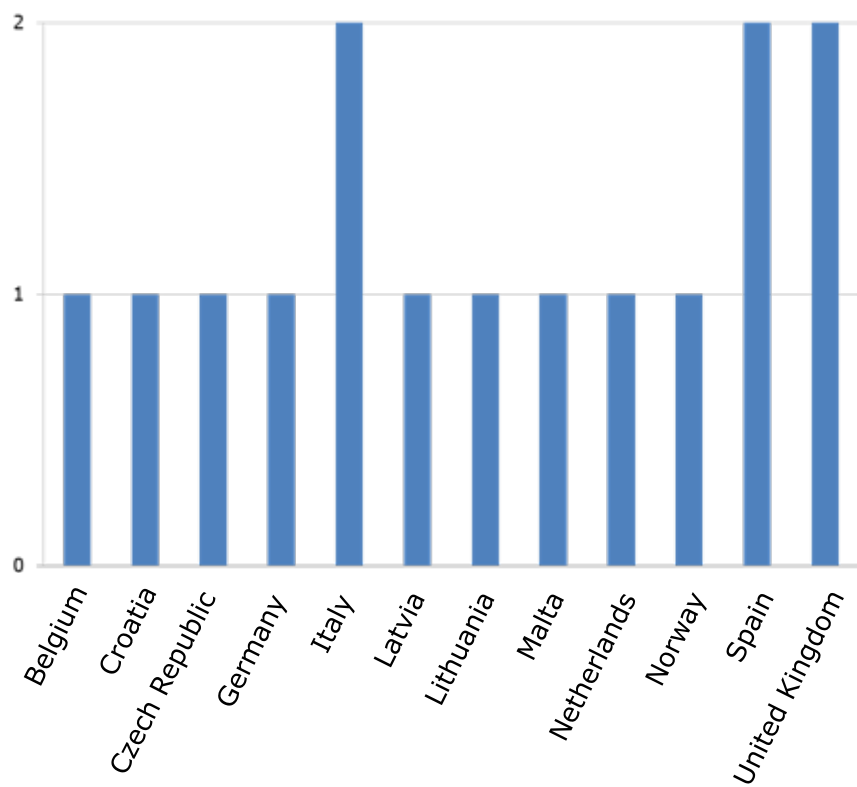
The vast majority of responses from individuals, 13 out of 15, identified themselves as professionals working in an area related to breast cancer. No one identified him/herself as a patient/consumer or family member. Two individuals asked for anonymisation of their contribution and another two individuals asked for confidential treatment of their contribution.

Figure 2. Survey responses from individuals (n=15)



All responses, except one from Norway, came from EU individuals, representing 11 out of 28 Member States. All the respondents but one reported having become aware of the public call for feedback by the e-mail received from the JRC. Two of the 15 individuals happen also to be nominated ECIBC National Contacts.

Figure 3. Geographical distribution of survey responses from individuals (n=15)



Forty-eight contributions were received from organisations, corresponding to 46 different entities. Kooperationsgemeinschaft Mammographie (Mammography Cooperative) and Deutsche Akkreditierungsstelle GmbH (DAkkS) contributed with two responses each. Their answers are counted twice in the pie-charts, whilst they are counted once when the number of organisations is reported in the text. Of the 48 responses on behalf of organisations, most of them came from professional societies or organisations (23%), from national accreditation bodies (NABs) (19%), and healthcare organisations (13%). Replies were received from ECIBC National Contacts from five countries. Fourteen entities asked for anonymisation of their contributions and five entities asked for the confidential treatment of their contributions.

Figure 4. Survey responses from organisations, according to the type of organisation (n=46)

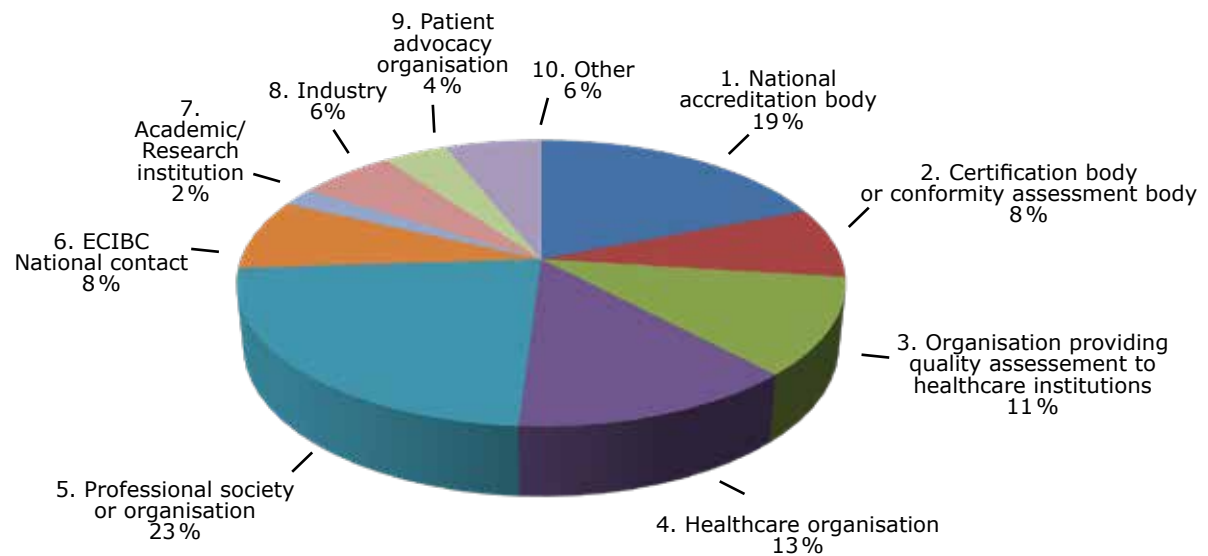


Table 1. List of organisations contributing to the call for feedback and not asking for anonymisation or confidentiality.

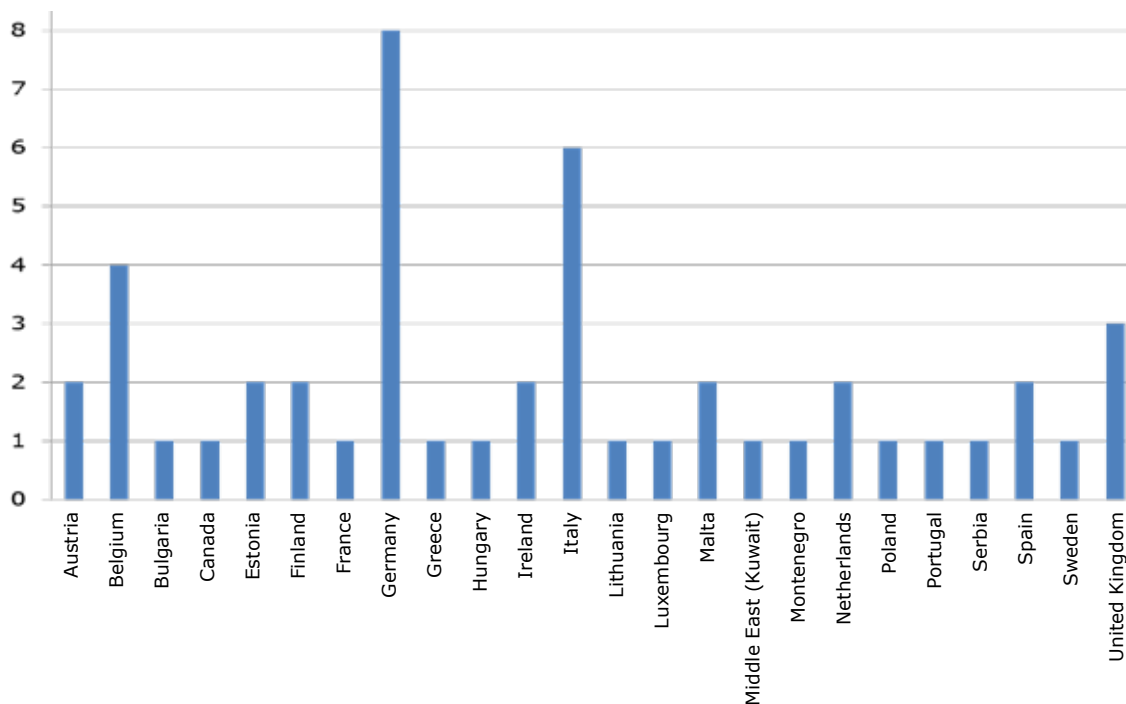
NAME	TYPE	COUNTRY
Accreditation Canada	Organisation providing quality assessment to healthcare institutions (e.g. hospital accreditation, breast cancer certification)	Canada
Association of Breast Surgery of Great Britain and Ireland (ABSGBI)	Professional society or organisation	UK
Associazione Senonetwork Italia Onlus	Professional society or organisation	Italy
Bulgarian Association for Medical Oncology	Professional society or organisation	Bulgaria
Catalan Cancer Plan. Catalonia. Spain	ECIBC National contact	Spain
Department of Cancers screening, Ministry of Health	Organisation providing quality assessment to healthcare institutions (e.g. hospital accreditation, breast cancer certification)	Luxembourg
Deutsche Akkreditierungsstelle GmbH (DAkKS)	National accreditation body	Germany
East Tallinn Central Hospital	Healthcare organisation (e.g. hospital, local health authority)	Estonia
Erasmus University Medical Center Rotterdam	Healthcare organisation (e.g. hospital, local health authority)	Netherlands
Estonian Society of obstetrics and Gynaecologists	Healthcare organisation (e.g. hospital, local health authority)	Estonia
European Association for Palliative Care	Professional society or organisation	Finland
European CanCer Organisation (ECCO) response on this occasion is based on input from European Society for Medical Oncology (ESMO), European Society of Surgical Oncology (ESSO), European Society for Radiotherapy & Oncology (ESTRO), European Oncology Nursing Society (EONS) and European Association of Nuclear Medicine (EANM)	Professional society or organisation	Belgium
European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services (EUREF)	Certification body or conformity assessment body	Netherlands

NAME	TYPE	COUNTRY
European Society for Medical Oncology (ESMO), European Organisation for Research and Treatment of Cancer (EORTC) and Champalimaud Foundation	Healthcare organisation (e.g. hospital, local health authority)	Portugal
European Society for Radiotherapy & Oncology (ESTRO)	Professional society or organisation	Germany
European Society of Breast Cancer Specialists (EUSOMA)	Professional society or organisation	Italy
European Society of Radiology	Professional society or organisation	Austria
German Cancer Society - Working Group of Pathology	Professional society or organisation	Germany
Ghent University hospital — on behalf of the breast care nurses and clinical nurse specialists	Academic / Research institution	Belgium
ITALCERT Srl	Certification body or conformity assessment body	Italy
Kooperationsgemeinschaft Mammographie (Mammography Cooperative)	Organisation providing quality assessment to healthcare institutions (e.g. hospital accreditation, breast cancer certification)	Germany
Ministry of Health of Republic Lithuania	Other	Lithuania
Office of Chief Medical Officer, Budapest, Hungary	ECIBC National contact	Hungary
OnkoZert GmbH	Certification body or conformity assessment body	Germany
Pfizer	Industry	Belgium
Sociedad española de senología y patología mamaria	Professional society or organisation	Spain
'Survive & Thrive' initiative for cancer patients support	Patient advocacy organisation	Kuwait

Responses came from 20 EU countries, two European countries outside the EU (Montenegro, Serbia) and two non-European countries (Canada, Kuwait). The two countries with the highest number of contributors were Germany (eight, from five different organisations) and Italy (six, from six organisations).

The respondents indicated they became aware of the public call for feedback mainly through the e-mail received from the JRC; other sources reported included references to DG SANTE's newsletter and personal communication from a colleague.

Figure 5. Geographical distribution of survey responses from organisations (n=48). In total, individuals and organisations from 23 out of 28 Member States (82 %) contributed to this public call for feedback



In the following paragraphs the results of the call for feedback will be reported question by question. Thereby the comments will be presented in an aggregated manner first, followed by a box, showing QASDG's response to the comments. As already stated, the complete original version of the contributions, with the exception of confidential ones, is available through the ECIBC web hub.

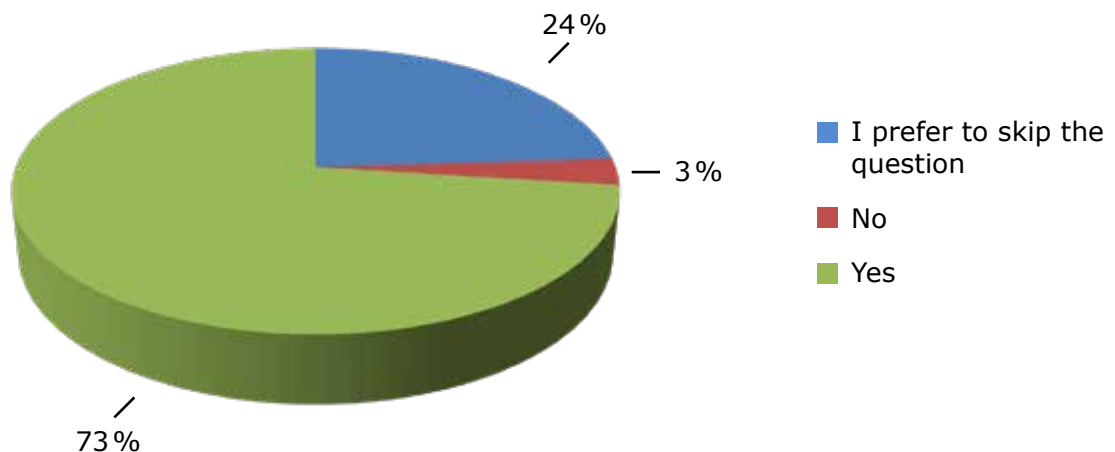
3.2 Use of accreditation standards for the *European QA scheme*

3.2.1 Standard ISO 17065:2012

The first question on the *European QA scheme* investigated whether the respondent agreed with the use of the standard ISO/IEC 17065:2012 for accreditation of certification bodies that will run the scheme.

Thirty-five organisations and 12 individuals (response rate: 76 %) responded. All responses but one were in favour of the use of this standard. We cannot report the comments supporting the negative reply, as it came from an individual asking for confidential treatment of his/her contribution.

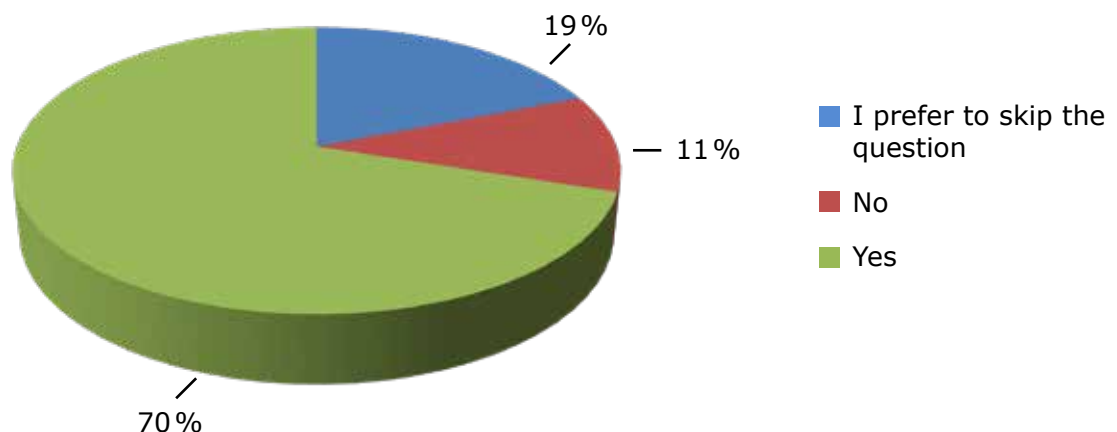
Figure 6. Agreement with the use of standard ISO/IEC 17065:2012. All the respondents (n=63)



3.2.2 Standard ISO 15189:2012

This question investigated whether the respondent agreed with the use of the standard ISO 15189:2012 for accreditation of testing and examination activities. Thirty-seven organisations and 12 individuals (81% in total) responded. Only six (11%) disagreed with the use of this standard.

Figure 7. Agreement with the use of standard ISO 15189:2012. All the respondents (n=63)



Two main concerns were raised by respondents on the use of ISO 15189:2012 accreditation and were associated with negative replies.

- Existence of other standards on testing services already in use and appropriate to the context. These other standards can be either inside the *European legislation for accreditation* (ISO/IEC 17020:2012 inspection for pathology laboratories in Germany — comment submitted by DAkkS, German Cancer Society - Working Group of Pathology, OnkoZert GmbH, and a contributor requiring anonymisation), or outside (i.e. Biomedical Laboratory and Diagnostic Imaging standards in the Accreditation Canada's Qmentum International Accreditation Program — comment submitted by Accreditation Canada).

- Direct application of ISO 15189:2012 to imaging services as this standard was developed for medical laboratories (comment submitted by Accreditation Canada).

Among those agreeing on the application of ISO 15189:2012 accreditation for testing services, similar concerns were also raised together with the suggestion, from the Kooperationsgemeinschaft Mammographie (Mammography Cooperative), to restrict the use of ISO 15189:2012 to outsourced services such as pathology, while imaging services within screening and diagnostics should simply be covered by the certification process.

In order to address the comments received, in particular those associated with negative replies and with concerns on the existence of other standards on testing services already in use, QASDG implemented a modification to *The Scope*, where a new sentence was added:

'For testing activities ISO 15189:2012 will be used. **Possible time and equivalence derogations will be covered within the Scheme Owner's requirements along the discussion and approval processes of the QASDG.**

Moreover, even if the *European QA scheme* is run under the *European legislation for accreditation*, the International Society for Quality in Healthcare (ISQua) is one of the reference models, as already mentioned in *The Scope*:

'The Manual may be inspired by recommendations such as the ones from the ISQua International Accreditation Programme (IAP).'

ISO 15189:2012 is already implemented for imaging services in at least two countries: the United Kingdom (via the Imaging Services Accreditation Scheme (ISAS) standard) and New Zealand. Please refer to the following websites for further information:

<https://www.isas-uk.org/>

<http://www.ianz.govt.nz/services/accreditation-2/accreditation/laboratories/medical/>

Finally, regarding the suggestion received on restricting the use of ISO 15189:2012 to outsourced services, according to ISO 17065:2012, an already accredited ISO 15189:2012 imaging process must not be certified, having 'presumption of conformity' to certification's management requirement (according to Sept. 2009 IAF ILAC ISO Joint Communiqué). Accreditation to ISO 15189:2012 should be 'complete' and cannot be restricted only to a sub-process such as outsourcing services being, these services, included in ISO 15189:2012 requirements.

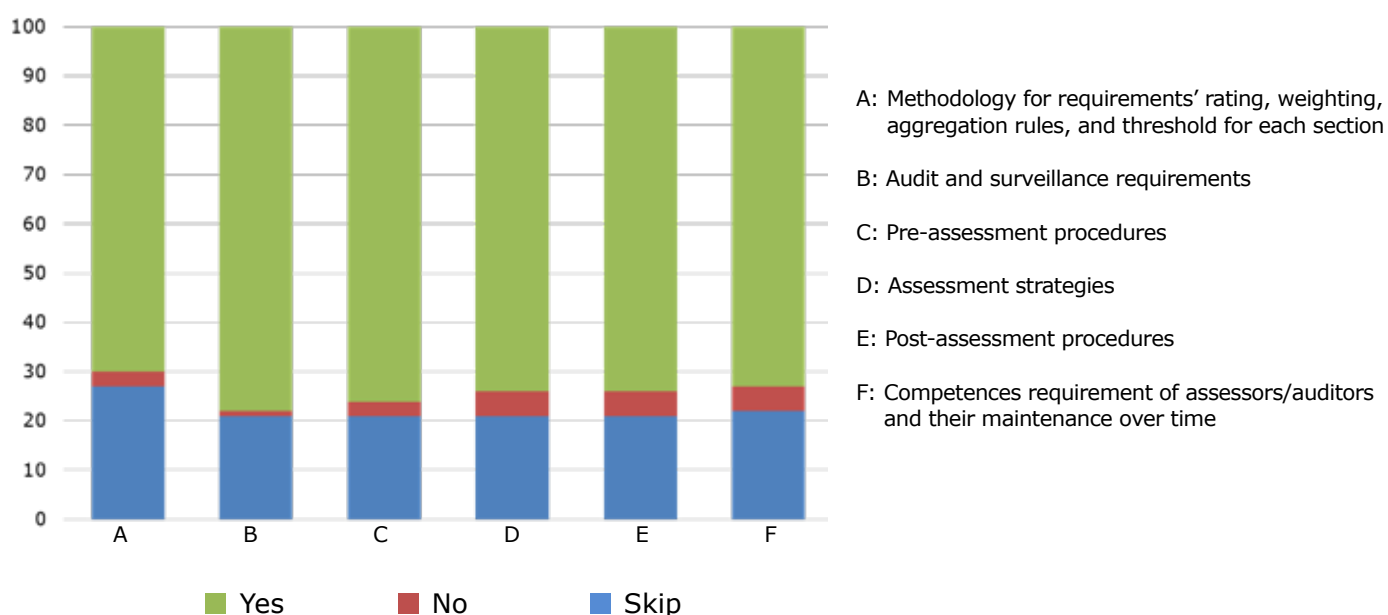
3.2.3 Certification scheme requirements (scheme owner requirements)

This question investigated whether the proposed scheme owner requirements were considered relevant. Respondents were asked to rate each scheme owner requirement with 'yes' or 'no' or 'skip this question'.

Seventy-nine per cent of respondents rated each requirement as 'yes' or 'no'. Some of the respondents who agreed with the proposed requirements also added comments, e.g. 'prioritization of requirements through a «weighting» system' (Accreditation Canada), 'a steering committee to govern the audits' (contribution from an organisation requiring anonymisation), 'direct observation in screening performance at site (visit) including review of interval cancers, review of clinically worked-up cases, and attending multidisciplinary meeting' (European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services — EUREF).

Concerns reported by respondents disagreeing with some of the proposed requirements often related to the fact that these would depend on national characteristics. In particular, these concerns arose with the auditing strategies, the composition of auditor teams, availability of external experts, format and style of reports, award decisions or appeals to award decisions (comments submitted by Kooperationsgemeinschaft Mammographie).

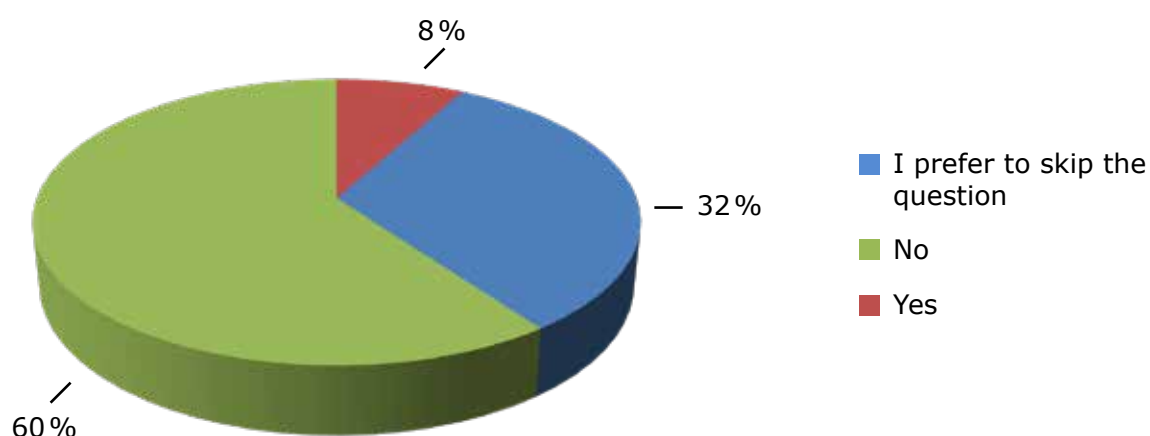
Figure 8. Relevance of scheme owner requirements. All the respondents (n=63)



Two-thirds of respondents declared that no further scheme owner requirements would be needed.

Two organisations suggested possible additional scheme owner requirements: 'Checklist for cancer patients to fill to confirm their awareness of the complete process of their service' (comment submitted by 'Survive & Thrive' initiative for cancer patients support); 'Having a clear goalsetting before starting a quality assurance' and 'Follow up sessions: internal and with external auditors' (comments submitted by Ghent University hospital on behalf of the breast care nurses and clinical nurse specialists). One individual suggested that 'Additional requirements not currently foreseen may emerge as the scheme develops and should be added as necessary'. One entity proposed an additional scheme owner requirement, but asked for confidential treatment of its contribution.

Figure 9. Need for other scheme owner requirements. All the respondents (n=63)

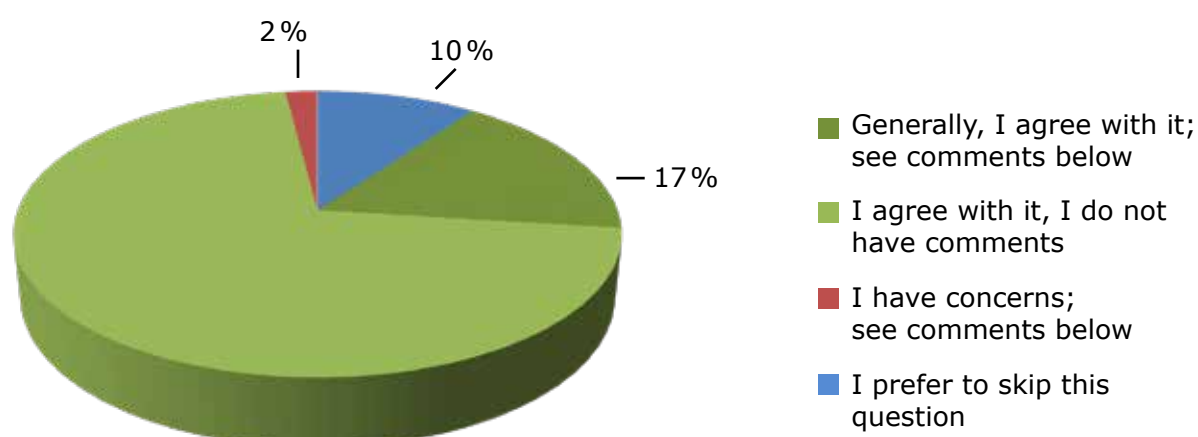


3.3 Services, interventions and diseases covered by the *European QA scheme*

No changes were implemented to *The Scope* regarding the scheme owner requirements. However, all the suggestions and comments received on scheme owner requirements will be discussed by QASDG for the preparation of a specific document on scheme owner requirements, which is foreseen to be issued together with the *European QA scheme* Manual. ECIBC National Contacts will be involved in evaluating the feasibility of the *European QA scheme* before it is piloted, and those breast cancer services selected for piloting will also contribute to ensuring that the *European QA scheme* will be implementable in all countries.

This question focused on services, interventions and diseases that the *European QA scheme* covers. Forty-two organisations and 13 individuals (90% of total respondents) answered this question. Close to 90% of respondents were in favour of the proposal made in *The Scope*.

Figure 10. Agreement with services, interventions and diseases covered. All the respondents (n=63)



Only one organisation (Pfizer) expressed concerns, commenting on the application of the *European QA scheme* to treatments. Concerns related, in particular, to the use of medicines, the interaction with the medicines regulatory framework (governed by the European Medicines Agency and national regulators) and the divergent availability of medicines in different countries due to e.g. a lack of reimbursement.

Among the other comments received, the main concerns were about the inclusion of diseases and the inclusion/modification/clarification of services in the *European QA scheme*:

- male breast cancer (input received from Association of Breast Surgery of Great Britain and Ireland - ABSGBI)
- benign breast diseases (input received from ABSGBI)
- education before screening (input received from two organisations requesting anonymisation)
- possible inclusion of general practitioner referral of symptomatic women (Kooperationsgemeinschaft Mammographie and Catalan Cancer Plan)
- surveillance should be moved after rehabilitation (Catalan Cancer Plan)
- clarifications about primary prevention vis-à-vis the ECIBC's proposed pathway (The Office of the Chief Medical Officer (Budapest) and the Catalan Cancer Plan).

More details on processes, addressing the comments received on treatment and screening, will not be apparent in *The Scope*, but will be covered in future QASDG documents. In particular, citizens' education for screening is considered to be included in the subprocess 'Patient involvement-empowerment' (e.g. 'communication of the diagnosis and treatment plan, patient information, patient navigation, shared decision making'), whilst primary prevention is included in the new subprocess called 'Primary prevention and health promotion'.

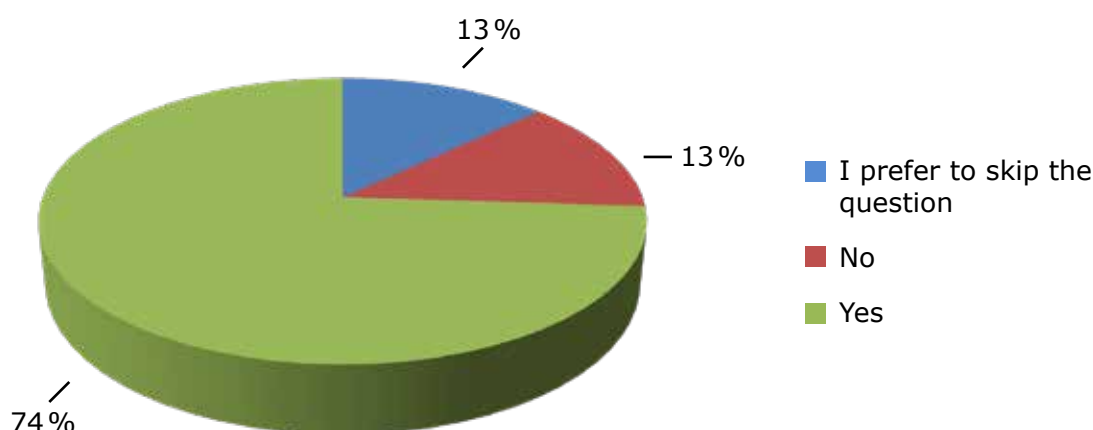
Male breast cancer and benign breast diseases do not fall under *the scope* of the *European QA scheme*. However, its blueprint may be adapted to breast cancer in male subjects in the context of a future project following the pilot run for female breast cancer, whilst other non-malignant breast diseases are covered by the scheme when implied in a differential diagnosis of cancer.

3.3.1 Breast cancer care pathway

This question investigated whether the breast cancer treatment pathway proposed was considered applicable in the respondent's own country. Thirty-nine organisations and 15 individuals (87% of the total) provided an answer, representing a total of 22 countries out of the 23 covered.

Almost three-quarters of respondents (74%) found the proposed pathway applicable in their country. Eight respondents (2 individuals and 6 organisations) from 6 countries (Belgium, Finland, Germany, Malta, Luxembourg, the Netherlands) declared that the pathway would not be applicable. A comment from Germany, received by one of the two responding individuals, could not be considered as it did not address the topic of the question.

Figure 11. National applicability of breast cancer care pathway. All the respondents (n=63)



All other comments addressed non-country-specific issues, and expressed suggestions or disagreements with one or more of the features of the breast cancer care pathway. For example, suggestions were received on:

- adding an arrow from the diagnosis box back to screening (input received from Erasmus University Medical Center Rotterdam);
- having a dedicated pathway for metastatic breast cancer (input received from Pfizer);
- mentioning the context of healthcare — e.g. 'What is happening in the hospital'; 'Which phase is situated in primary care' (input received from Ghent University hospital on behalf of the breast care nurses and clinical nurse specialists);
- adding 'death as an outcome' at any step after diagnosis (input received from the Department of Cancers screening, Ministry of Health, Luxembourg).

The European Association for Palliative Care (EAPC) used the free-text box at the end of the questionnaire to express a request for a better definition of 'palliative care'.

3.3.2 Subprocesses

For this section two questions were addressed: the first investigated whether the proposed subprocesses were considered relevant; the second asked for suggestions on additional subprocesses that may be needed.

Forty-three organisations and 12 individuals (response rate 87%) replied to the first question and 74% of respondents felt the proposed subprocesses were relevant.

Thirty-six organisations and 12 individuals (response rate 78%) replied to the second question and 49% believed that additional subprocesses were not needed, whilst 29% proposed additional subprocesses.

Suggestions for modifications, deletions or addition of subprocesses were first screened by the

JRC, the QASDG chair, the vice-chair and the coordinators of the subgroup for *Organisation, scope and modules*, the subgroup on *Certification Processes*, and the subgroup on *Quality concepts and Keywords* (glossary). The suggestions considered as relevant for a discussion by QASDG were presented at the 16 March 2016 meeting and then approved or rejected by QASDG. Details on the decision procedure are reported in the meeting’s minutes⁹ and the results are summarised in the box below.

Figure 12. Relevance of subprocesses. All the respondents (n=63)

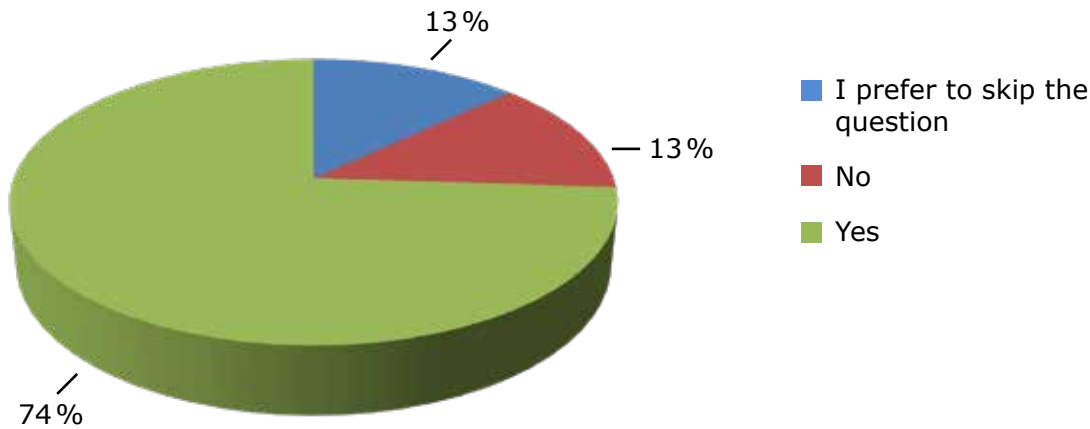
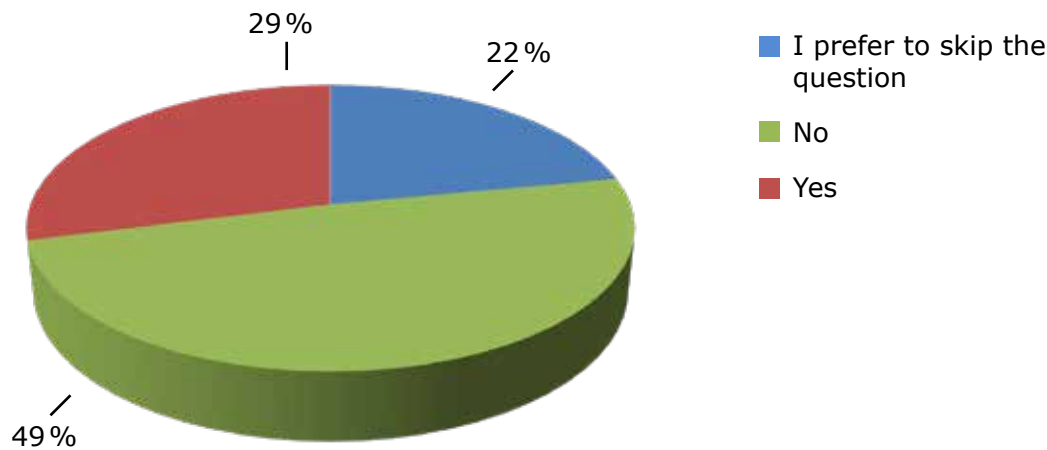


Figure 13. Need for additional subprocesses. All the respondents (n=63)



9 See footnote 8

The most significant changes to *The Scope* following the review process triggered by this part of the call for feedback included the following:

- Inclusion of a new subprocess named 'Prevention and health promotion' (prompted by inputs received in other sections of the questionnaire from two organisations requiring anonymisation).
- Inclusion of a new subprocess named 'Governance' (prompted by input from an individual).
- Renamed the imaging subprocess as 'Imaging and imaging-guided interventions' (prompted by input from the European Society of Radiology).
- Added a new subprocess 'Quality assurance of equipment imaging and therapy devices' (prompted by input from an entity requiring anonymisation).
- Added a new subprocess called 'Fertility preservation' (prompted by input from an entity requiring anonymisation).
- Added 'Medications management' to the subprocess 'Patient safety' (prompted by input from an individual).

Most of the other subprocesses suggested in the feedback were already considered by the existing ones, *e.g.*:

- 'Breast Information systems to track and store patient data' (input received from two entities requiring anonymisation) within 'Data management (databases and registries)';
- 'Document control' (input received from an entity requiring anonymisation) within 'Quality Management';
- 'Patient and family engagement' (Accreditation Canada) within 'Patient involvement-empowerment';
- 'Information transfer' (Accreditation Canada) within 'Team collaboration including: multidisciplinary meeting / tumour board';
- 'Handover' within 'Data management (databases and registries)'.

Two entities requiring anonymisation suggested a list of specific imaging techniques to be separately included. In this case QASDG considered that the suggestions were globally covered by the 'Imaging and imaging-guided interventions' and the 'Quality assurance of equipment imaging and therapy devices' subprocesses.

A further entity requiring anonymisation made suggestions on the allocation of subprocesses to the six main processes of care. In this case, all the corrections suggested were implemented except the one asking to delete the complementary and integrative approach subprocess from the screening process, because in this case use of complementary approaches should be intended as contributing to the control of anxiety during the assessment phase.

Also a comment on the subprocess 'symptom control' in the screening process, submitted by ESMO, EORTC, Champalimaud Foundation and ECCO in the free-text box at the end of the questionnaire, was not addressed with a modification in *The Scope*, because symptom control in screening is to be intended as pain control during mammography, addressing anxiety, etc.

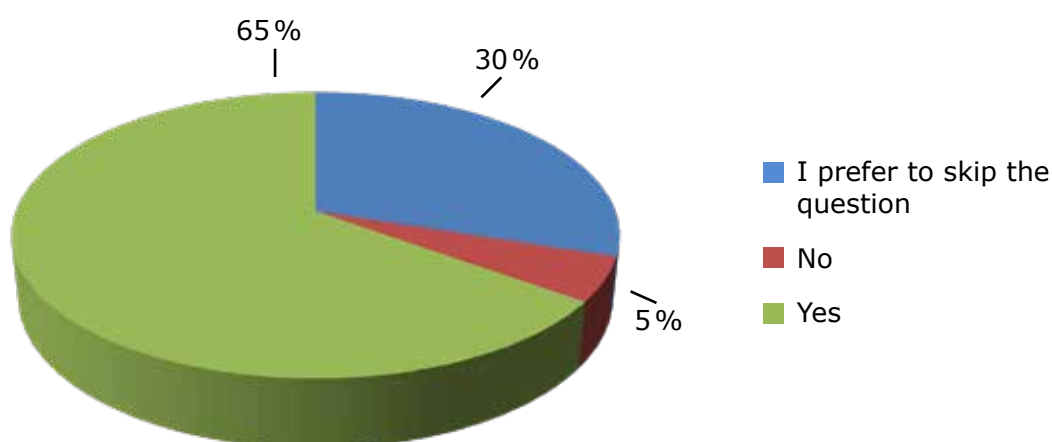
3.4 The modular approach

The first question investigated whether the modular approach proposed was considered applicable in the respondent's own country. Thirty-one organisations and 12 individuals (response rate 70%) responded, representing a total of 21 EU countries, plus Norway and Serbia.

All the respondents, except for one (an entity requiring anonymisation), considered the modular approach applicable in their countries. However, two other respondents from the same country instead stated that the modular approach proposed would be applicable.

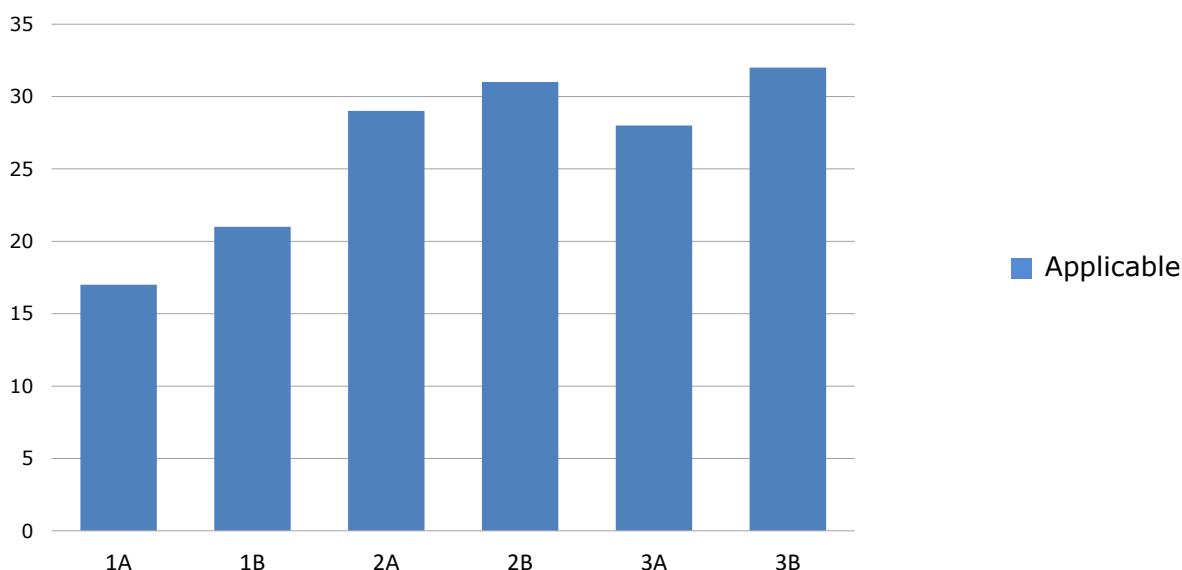
An entity requiring anonymisation replied that none of the outlined options would be feasible in Germany due to the preconditions of the healthcare system. However, the option closest to applicability would be option 3B, the entity stated.

Figure 14. Applicability of the modular approach. All the respondents (n=63)



The second question asked respondents to indicate whether the proposed scenarios would be implementable in their country. Thirty-five entities (12 individuals and 23 organisations) responded.

Figure 15. Applicability of scenarios. Valid responses (n=35)



The two scenarios where the breast cancer screening programme and the breast centre are under the same legal entity (1A and 1B) were seen as less implementable with respect to the other ones, although around half of the respondents declared the two scenarios were anyway implementable.

Scenarios characterised by the networking model received the most consensus concerning applicability, both with end-of-life care being integrated in the breast centre and with not being integrated.

In order to guarantee the implementability of the *European QA scheme* in each European country, it is in principle sufficient that a single modular scenario is applicable in a given country. As this is apparently the case, according to the replies received, no changes were made to this part of *The Scope*.

Table 2. Individual respondents' replies on the applicability of the scenarios

Country	Organisation	1A	1B	2A
Austria	European Society of Radiology	Applicable	-	Applicable
Belgium	Ghent University hospital - on behalf of the breast care nurses and clinical nurse specialists	Applicable	Applicable	Applicable
Belgium	Anonymous entity	Not applicable	Applicable	Applicable
Bulgaria	Bulgarian Association for Medical Oncology	Not applicable	Not applicable	Applicable
Estonia	East Tallinn Central Hospital	Applicable	Applicable	Applicable
Estonia	Estonian Society of Obstetricians and Gynaecologists	Applicable	Applicable	Applicable
Finland	European Association for Palliative Care	Not applicable	Not applicable	Applicable
Finland	Anonymous entity	-	-	Applicable
France	Anonymous entity	Not applicable	Applicable	Applicable
Germany	ESTRO	Not applicable	Applicable	Not applicable
Germany	Kooperationsgemeinschaft Mammographie (Mammography Cooperative)	Not applicable	Not applicable	Not applicable
Germany	OnkoZert GmbH	-	Not applicable	-
Italy	Anonymous entity	Applicable	Applicable	Applicable
Italy	Associazione Senonetwork Italia Onlus	Not applicable	Not applicable	Applicable
Italy	ITALCERT Srl	Not applicable	Not applicable	Applicable
Italy	EUSOMA	Not applicable	Not applicable	Applicable
Lithuania	Ministry of Health	Applicable	Applicable	Applicable
Luxembourg	Department of Cancers screening, Ministry of Health	Not applicable	Not applicable	Not applicable
Netherlands	EUREF	Not applicable	Not applicable	Not applicable
Portugal	On behalf of ESMO, EORTC and Champalimaud Foundation	Applicable	Applicable	Applicable
Spain	Sociedad española de senologia y patologia mamaria	Applicable	Applicable	Applicable
Spain	Catalan Cancer Plan, Catalonia, Spain	Applicable	Applicable	Applicable
Sweden	Anonymous entity	Applicable	Applicable	Applicable

Country	Organisation	2B	3A	3B
Austria	European Society of Radiology	-	Applicable	-
Belgium	Ghent University hospital - on behalf of the breast care nurses and clinical nurse specialists	Applicable	Applicable	Applicable
Belgium	Anonymous entity	Applicable	Applicable	Applicable
Bulgaria	Bulgarian Association for Medical Oncology	Applicable	Applicable	Not applicable
Estonia	East Tallinn Central Hospital	Applicable	Applicable	Applicable
Estonia	Estonian Society of Obstetricians and Gynaecologists	Applicable	Applicable	Applicable
Finland	European Association for Palliative Care	Applicable	Applicable	Applicable
Finland	Anonymous entity	Applicable	Applicable	Applicable
France	Anonymous entity	Applicable	Applicable	Applicable
Germany	ESTRO	Applicable	Not applicable	Applicable
Germany	Kooperationsgemeinschaft Mammographie (Mammography Cooperative)	Applicable	Not applicable	Applicable
Germany	OnkoZert GmbH	Not applicable	-	Not applicable
Italy	Anonymous entity	Applicable	Applicable	Applicable
Italy	Associazione Senonetwork Italia Onlus	Applicable	Applicable	Applicable
Italy	ITALCERT Srl	Applicable	Applicable	Applicable
Italy	EUSOMA	Applicable	Applicable	Applicable
Lithuania	Ministry of Health	Applicable	Applicable	Applicable
Luxembourg	Department of Cancers screening, Ministry of Health	Not applicable	Not applicable	Applicable
Netherlands	EUREF	Applicable	Not applicable	Applicable
Portugal	On behalf of ESMO, EORTC and Champalimaud Foundation	Applicable	Applicable	Applicable
Spain	Sociedad española de senologia y patología mamaria	Applicable	Applicable	Applicable
Spain	Catalan Cancer Plan, Catalonia, Spain	Applicable	Applicable	Applicable
Sweden	Anonymous entity	Applicable	Applicable	Applicable

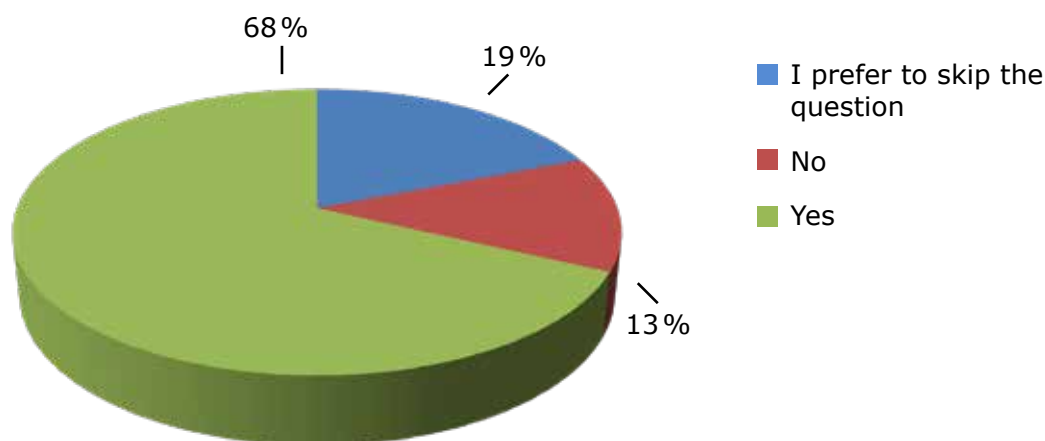
3.5 The *European QA scheme's* contents

3.5.1 The Manual of requirements and the indicators

The first question asked whether the description of the Manual of requirements was clear enough. Thirty-six organisations and 14 individuals (response rate 81 %) responded.

About two-thirds of respondents (68%) considered the description of the Manual to be clear. Most of the comments indicating that the Manual was not sufficiently clear concerned details that should be provided, in particular if and how existing requirements and quality indicators (EUSOMA) will be used as a starting point (input received from EUSOMA, from ECCO — the response on this occasion was based on input from ESMO, ESSO, ESTRO, EONS and EANM — and from an answer on behalf of ESMO, EORTC and the Champalimaud Foundation).

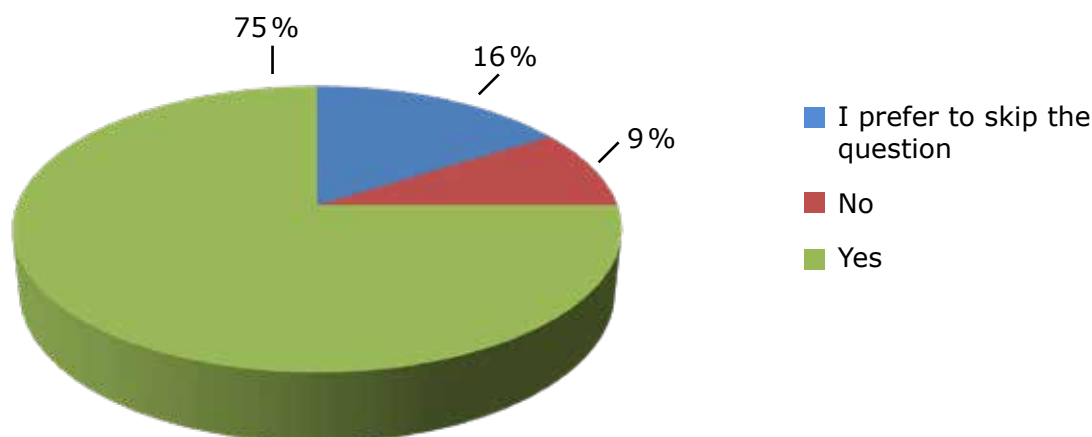
Figure 16. Clarity of Manual description. All the respondents (n=63)



The second question investigated whether respondents found that the description of the indicators was clear enough. Thirty-seven organisations and 15 individuals (response rate 84 %) responded.

Three-quarters (75%) considered that the description of the indicators was clear. The comments received from those disagreeing on the clarity of the indicators were similar to those received for the Manual. They asked in particular if and how existing quality indicators (EUSOMA) will be used as a starting point (input received from ECCO — the response on this occasion was based on input from ESMO, ESSO, ESTRO, EONS and EANM — and from an answer on behalf of ESMO, EORTC and the Champalimaud Foundation). An individual contributor suggested including not only quantitative indicators but also qualitative indicators such as patient satisfaction, self-management patient and partner, knowledge and expertise professionals, etc., and having a minimal set of indicators such as clinical outcomes, patient outcomes, process outcomes, professional outcomes, organisation outcomes, and network outcomes.

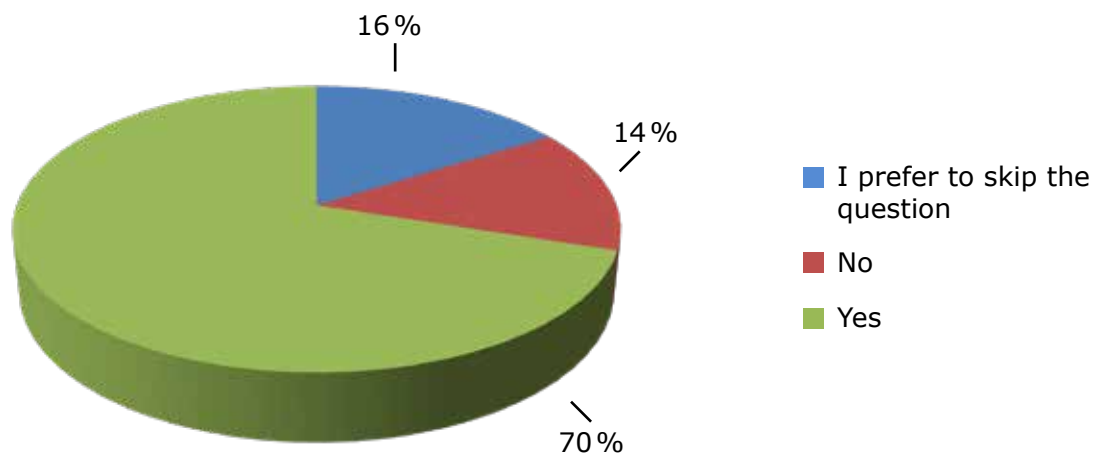
Figure 17. Clarity of indicator description. All the respondents (n=63)



Finally, the questionnaire asked whether the description of the methods for the development of requirements and indicators was considered clear. Thirty-seven organisations and 15 individuals (84% of the total) responded.

More than two-thirds (70%) considered the description of the method for the development of requirements and indicators as clear.

Figure 18. Clarity of the description of the methods for the development of requirements and indicators. All the respondents (n=63)



Comments stating that the methods were not clearly described were similar to those received for the Manual and indicators, in particular asking for more details that should have been provided, and if and how existing quality indicators (EUSOMA) will be used as a starting point (input received on behalf of ESMO, EORTC and Champalimaud Foundation and from ECCO). Details that were suggested for inclusion in the methodology were:

- A SMART (Specific – Measurable – Assignable – Realistic – Time-related) description of indicators and more examples (input received from Ghent University hospital on behalf of the breast care nurses and clinical nurse specialists, Belgium).

- More references to the Delphi-like rounds and how they translate into a valid and reliable result (input received from an individual).
- How understandability, measurability, behaviourability and achievability of indicators (all listed in the RUMBA criteria) are addressed by the Delphi-like rounds (input received from the Catalan Cancer Plan, Catalonia, Spain).
- Who will be included in the Delphi-like rounds and how long this process is expected to take (input received from an individual).

A specific document on the project's methodology was made available on the ECIBC website: <http://ecibc.jrc.ec.europa.eu/-/methods-of-the-voluntary-european-quality-assurance-scheme-for-breast-cancer-services>

In this document the aspects reported as unclear by the respondents are now explained. For example, from this document it may be inferred that the EUSOMA requirements and quality indicators will be considered, together with requirements and indicators from other existing quality schemes, for inclusion in the source requirements that will be used for the Delphi-like rounds.

In the list of documents serving as a basis for the Manual, only non disease-specific guidance for the development of healthcare quality recommendations is cited (i.e. from the ISQuA and from the National Institute for Health and Care Excellence), as such general guidance provides the theoretical frame for structuring breast cancer specific-requirements, for instance along quality dimensions. For this reason, none of the existing breast cancer-specific sets of requirements and indicators, including EUSOMA, are cited in this part of *The Scope*.

3.5.2 Reference documents

Via this question respondents were asked to suggest further reference documents that might be needed. Thirty-one organisations and 11 individuals (response rate 67 %) responded.

Almost half of the respondents (49%) found that additional reference documents were not needed, whilst 18% proposed additional reference documents.

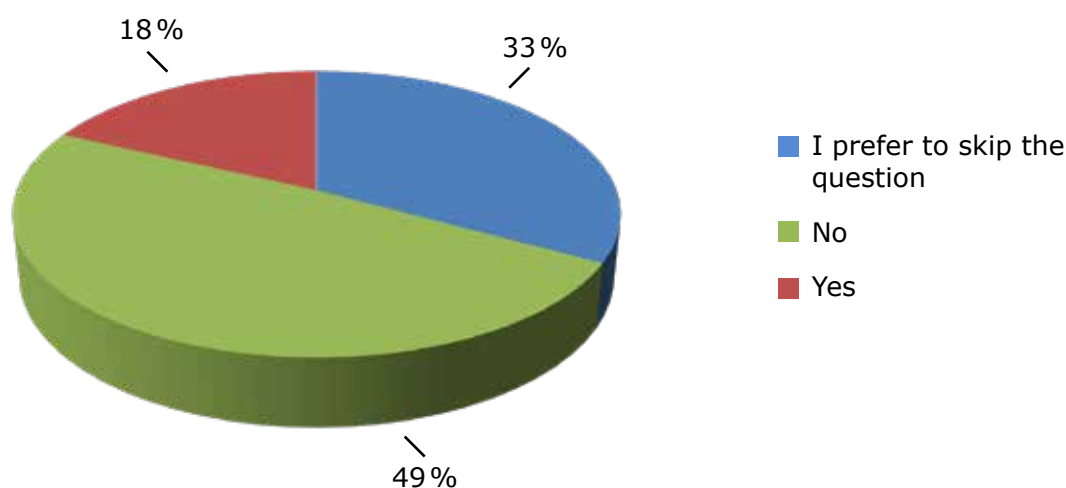
In two cases, the respondent (an individual and an entity that required anonymisation) suggested a general category of reference documents that may be needed: 'Psycho-social screening and assessment in oncology and palliative care settings' and 'Guidelines for breast cancer for whole breast cancer service (treatment, rehabilitation...)'.

In all the other cases, the respondents indicated specific documents to be considered as reference documents:

- 'ESMO Guidelines Early Breast Cancer' (input received from ESMO, EORTC and Champalimaud Foundation, and from ECCO);

- 'St Gallen Consensus Guidelines Primary Breast Cancer' (input received from ESMO, EORTC Champalimaud Foundation, and from ECCO);
- 'ESO-ESMO Guidelines for Advanced Breast Cancer' (input received from ESMO, EORTC and Champalimaud Foundation, and from ECCO);
- 'National Comprehensive Cancer Network Guidelines for Breast Cancer' (input received from ESMO, EORTC and Champalimaud Foundation, and from ECCO);
- 'Swedish National Guidelines for treatment of breast cancer' and 'National Clinical Practice Guidelines' for breast cancer (input received from an entity requiring anonymisation).

In the final free-text box for comments, an entity requiring anonymisation suggested the Health Information and Quality Authority's 'National Standards for Safer Better Healthcare' for information on quality themes and capability and capacity themes.



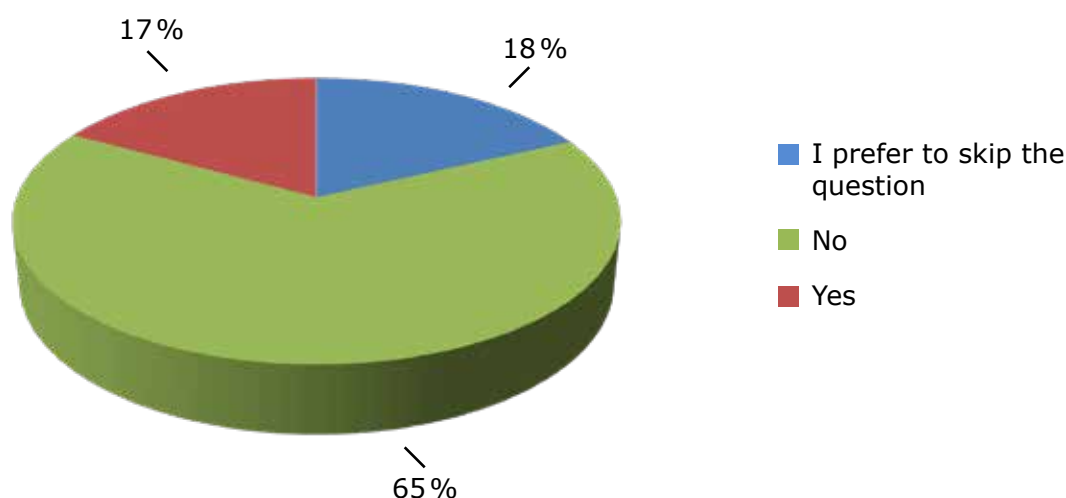
The comment on the need of psycho-social screening and assessment reference documents will be taken into account for the broader reference documents category *Core set of information to be recorded in the different processes of care, such as: [...]* d) medical records.

All the guidelines mentioned in the responders' comments will be taken into account either via the call for reference documents or via the evaluation for inclusion in the ECIBC Guidelines Platform (3).

Figure 19. Need for other typologies of reference documents. All the respondents (n=63)

3.5.3 Quality domains

This question asked the respondent to suggest further quality domains that might be appropriate for the *European QA scheme*. Thirty-nine organisations and 12 individuals (response rate 82 %) responded.



The majority of respondents (65%) did not consider the need for additional quality domains, whilst 17% proposed additional quality domains.

Figure 20. Need for more quality domains. All the respondents (n=63)

As already seen for subprocesses, suggestions for modifications, deletions or addition of quality domains were first screened by the JRC, the QASDG chair, the vice-chair and the coordinators of the subgroup for *Organisation, scope and modules*, the subgroup on *Certification Processes*, and the subgroup on *Quality concepts and Keywords (glossary)*. The suggestions considered as relevant for a discussion by QASDG were presented at the 16 March meeting and then approved or rejected by QASDG. Details on the decision procedure are reported in the meeting's minutes¹⁰.

The additional quality domains proposed were:

- professional competencies (input received from an entity requiring anonymisation);
- patients awareness and prevention (input received from the 'Survive & Thrive' initiative);
- cost-effectiveness (input received from ESMO, EORTC and the Champalimaud Foundation, and by ECCO);
- medical devices (input received from an entity requiring anonymisation);

¹⁰ See footnote 7

- quality-of-life (input received from the European Association for Palliative Care);
- use of information (input received from an entity requiring anonymisation);
- multidisciplinary protocols (input received from Ghent University hospital on behalf of breast care nurses and clinical nurse specialists, Belgium)
- education and expertise of professionals (input received from Ghent University hospital on behalf of breast care nurses and clinical nurse specialists, Belgium);
- vision of the breast cancer centre — management (input received from Ghent University hospital on behalf of breast care nurses and clinical nurse specialists, Belgium)

One individual and Pfizer included a comment on the 'clinical effectiveness' domain in the free-text box at the end of the questionnaire. These comments required to clarify and/or broad the scope of this domain.

QASDG decided not to change the quality domains already proposed in *The Scope*. Cost effectiveness was considered an important issue and a new sentence was added to *The Scope*: 'Cost-effectiveness is also an important dimension of service provision that should be taken into account in the *European QA scheme*'.

A new reference to the Organisation for Economic Co-operation and Development (OECD) definition was added to the quality domain for 'clinical effectiveness'.

Other suggestions were considered to be already addressed by other quality domains or in the list of subprocesses:

- The 'Facilities, resources and workforce' domain may also include 'Professional competencies' and 'Education and expertise of professionals'.
- The 'Personal empowerment and experience' domain may also include 'Patients awareness and prevention' and 'Quality-of-life'.
- 'Team collaboration including: multidisciplinary meeting/tumour board' and the 'Handover' subprocess may also include 'Multidisciplinary protocols'.
- 'Data management databases and registries' may also include 'Use of information'.
- The new 'Governance' subprocess may also include 'Vision of the breast cancer center – management'.
- The 'Medical devices' domain is considered to be transversely addressed in the different subprocesses.

3.6 General comments

Thirty-six respondents (twenty-nine organisations and six individuals) submitted a comment in the free-text box at the end of the questionnaire. Ten praised the ECIBC or *The Scope*, or thanked the JRC for providing the opportunity to give feedback. Most comments were constructive, even when expressing concerns, and no severe criticism of *The Scope* was expressed. In most cases the comments were linked to one of the sections of the previous questionnaire and in this Report they are reported in the specific paragraph.

A comment on the whole document (from the Office of Chief Medical Officer, Budapest, Hungary) addressed the language element, which was perceived as too technical. Future versions of *The Scope* and of other ECIBC's outputs will also be developed in user-friendly language, in order to be more easily understood by all stakeholders.

4. Conclusion

Globally, the results of this public call for feedback indicate that respondents appreciated the openness of the procedure and, in fact, this same degree of transparency will be applied throughout the ECIBC.

Overall, respondents represented the main categories of stakeholders (see Figure 4) and expressed acceptance and positive consideration of the main features of the *European QA scheme* as presented in *The Scope*. On average, the percentage of respondents agreeing with the items proposed in *The Scope* was about 70 %, and the negative responses were usually below 10 %. These general figures suggest that no major changes to *The Scope* need to be made.

The JRC and QASDG carefully evaluated the feedback, in particular for the two points that were consistently raised by the respondents and/or countries:

- the applicability of ISO 15189:2012 as an accreditation standard for pathology laboratories in Germany, where this activity is considered as inspection and ISO/IEC 17020 is used;
- a lack of detailed information on the methodology proposed for the selection of requirements and indicators, in particular regarding the use of existing requirement sets, like the one used by EUSOMA.

For the first point, *The Scope* was amended in order to allow for the use of other standards proving to be equivalent to ISO 15189:2012. In respect to the description of the methodology, a new document is available on the ECIBC web hub¹¹ describing in detail the processes of selecting requirements and indicators by using the Delphi methodology.

The relatively small number of replies received in total and, in particular, the lack of information from five EU Member States (Cyprus, Denmark, Romania, Slovakia and Slovenia) can be seen as a limitation to the significance of the results. However, the number and relevance of organisations (in some cases covering the whole Europe) contributing to this call for feedback can be considered as compensating factors for the limited number of replies and the five countries not covered.

On the other hand, the JRC will put in place a strategy to favour a wider coverage of the 34 countries involved in the project, in particular for future steps relating to implementation (e.g. the scheme piloting).

The new version of *The Scope*, published together with this report, integrates a significant number of the inputs received and when feedback is not integrated, the reasons are clearly expressed in this Report.

The call for feedback has led to an enriched document, thanks to the diversity and meaningfulness of contributions. This call for feedback can thus be considered a success and hopefully contributes to enhancing the future implementation of the *European QA scheme* and its potential impact on the quality of breast cancer care in Europe.

A new call for feedback will be launched on publication of the first version of the *European QA scheme* Manual, likely in 2018.

11 <http://ecibc.jrc.ec.europa.eu/qa-methodology>

References

- (1) Neamțiu L, Deandrea S, Lerda D, López-Alcalde J, Ulutürk A. *European Commission Initiative on Breast Cancer - ECIBC. Organisation of project guiding and support meetings.* European Commission, Office for Official Publications of the European Communities, Luxembourg; 2014.
- (2) Neamțiu L, Bramesfeld A, Deandrea S, Lerda D, López-Alcalde J, Pyllkanen L, Saz-Parkinson Z, Ulutürk A. *European Commission Initiative on Breast Cancer - ECIBC. Organisation of project guiding and support meetings.* European Commission, Office for Official Publications of the European Communities, Luxembourg; 2015.
- (3) Pyllkanen L, Ambrosio M, Bramesfeld A, Deandrea S, Neamțiu L, Saz-Parkinson Z, Lerda D. *The ECIBC Guidelines Platform for all breast care processes.* European Commission, Office for Official Publications of the European Communities, Luxembourg; 2016.

List of abbreviations

ABSGBI: Association of Breast Surgery of Great Britain and Ireland

DAkKS: Deutsche Akkreditierungsstelle GmbH

DG SANTE: Directorate-General for Health and Food Safety

EA: European co-operation for Accreditation

EANM: European Association of Nuclear Medicine

EAPC: European Association for Palliative Care

EC: European Commission

ECCO: European CanCer Organisation

ECIBC: European Commission Initiative on Breast Cancer

EONS: European Oncology Nursing Society

ESMO: European Society for Medical Oncology

ESSO: European Society of Surgical Oncology

ESTRO: European Society for Radiotherapy & Oncology

EUPHA: European Public Health Association

EUREF: European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services

EUSOMA: European Society of Breast Cancer Specialists

ISQua: International Society for Quality in Healthcare

JRC: Joint Research Centre

NAB: National Accreditation Body

OECD: Organisation for Economic Co-operation and Development

QASDG: Quality Assurance Scheme Development Group

List of figures

Figure 1. Distribution of responses to the public call for feedback.

Figure 2. Responses from individuals.

Figure 3. Geographical distribution of responses from individuals.

Figure 4. Responses from organisations.

Figure 5. Geographical distribution of responses from organisations.

Figure 6. Agreement with the use of standard ISO 17065:2012. All the respondents.

Figure 7. Agreement with the use of standard ISO 15189:2012. All the respondents.

Figure 8. Relevance of scheme owner requirements. All the respondents.

Figure 9. Need for other scheme owner requirements. All the respondents.

Figure 10. Agreement with services, interventions and diseases covered. All the respondents.

Figure 11. Applicability of breast cancer care pathway. All the respondents.

Figure 12. Relevance of subprocesses. All the respondents.

Figure 13. Need for additional subprocesses. All the respondents.

Figure 14. Applicability of the modular approach. All the respondents.

Figure 15. Applicability of scenarios. Valid responses.

Figure 16. Clarity of Manual description. All the respondents.

Figure 17. Clarity of indicator description. All the respondents.

Figure 18. Clarity of the description of the methods for the development of requirements and indicators. All the respondents.

Figure 19. Need for other typologies of reference documents. All the respondents.

Figure 20. Need for more quality domains. All the respondents.

List of tables

Table 1. List of organisations contributing to the call for feedback.

Table 2. Individual respondents' replies on the applicability of the scenarios.

Annex 1

Call for feedback on the scope of the European Quality Assurance scheme for Breast Cancer Services

Call for feedback on the scope of the European Quality Assurance scheme for Breast Cancer Services

Fields marked with * are mandatory.

From 17 February 2016 to 09 March 2016, the European Commission Initiative on Breast Cancer (ECIBC) is asking stakeholders for comments on the scope of the European Quality Assurance scheme for Breast Cancer Services.

Published:

17 February 2016

Privacy statement



I confirm that I read and agree with the Privacy statement.

[Privacy%20Statement%20%20JRC.pdf](#)

Respondent's information

* Your full name

250 character(s) maximum

* Your e-mail address for correspondence only (the e-mail address will not be disclosed under any circumstances, please refer to the privacy statement)

* I am replying:

- ☐ As an individual
- ☐ On behalf of an organisation (including any association, authority, company or body)

* Please select the category that you identify with best.

- ☐ Consumer or patient
- ☐ Family member or carer of a patient
- ☐ Professional working in areas related to breast cancer screening or diagnosis, such as radiologists, pathologists, epidemiologists, clinicians, policymakers, researchers, guideline developers
- ☐ Other

* Name of the organisation

250 character(s) maximum

* Please select the category that you identify with best.

- ☐ 1. Patient advocacy organisation
- ☐ 2. Healthcare organisation
- ☐ 3. Professional society or organisation, including guidelines development organisations
- ☐ 4. ECIBC National contact
- ☐ 5. Academic / Research institution
- ☐ 6. Trade union
- ☐ 7. Industry
- ☐ 8. Other

* Your country

- ☐ EU country
- ☐ Non EU country

* EU country

- ☐ Austria
- ☐ Belgium
- ☐ Bulgaria
- ☐ Croatia
- ☐ Republic of Cyprus
- ☐ Czech Republic
- ☐ Denmark
- ☐ Estonia
- ☐ Finland
- ☐ France
- ☐ Germany
- ☐ Greece
- ☐ Hungary
- ☐ Ireland

- ☐ Italy
- ☐ Latvia
- ☐ Lithuania
- ☐ Luxembourg
- ☐ Malta
- ☐ Netherlands
- ☐ Poland
- ☐ Portugal
- ☐ Romania
- ☐ Slovakia
- ☐ Slovenia
- ☐ Spain
- ☐ Sweden
- ☐ UK

Non EU country (please specify)

40 character(s) maximum

★ Do you agree to the publication of your contribution?

- ☐ Yes (I consent to the publication of my contribution together with my name, and I declare that none is subject to copyright restrictions that would prevent publication)
- ☐ Yes (I consent to the publication of my contribution in an anonymous manner, and I declare that none is subject to copyright restrictions that would prevent publication)
- ☐ No (the contribution cannot be published, but the contribution may be used internally within the Commission)

How you found out about this Call for feedback?

- ☐ E-mail from ECIBC
- ☐ DG SANTE newsletter
- ☐ Other (please mention)

Other source (please specify)

250 character(s) maximum

General scope of the *European Quality Assurance scheme for Breast Cancer Services*

1b. How accreditation is applied for the *European QA scheme*

*** Do you agree with the standard selected for the accreditation scheme (ISO17065:2012)?**

- ☐ Yes
- ☐ No
- ☐ I do not wish to answer this question

Please include your comments.

500 character(s) maximum

*** Do you agree with the standard selected for testing and examination activities (ISO15189:2012)?**

- ☐ Yes
- ☐ No
- ☐ I do not wish to answer this question

Please include your comments.

500 character(s) maximum

1c Certification scheme requirements (scheme owner requirements)

Are the certification scheme requirements mentioned appropriate?

	Yes	No
*Methodology for requirements' rating (e.g. numeric, Likert, non-conformity, etc.), weighting (if any), aggregation rules, and threshold scores for each section	<input type="radio"/>	<input type="radio"/>
*Audit and surveillance requirements (e.g. frequency of audit and composition of auditor team)	<input type="radio"/>	<input type="radio"/>
*Pre-assessment procedures (e.g. self-assessment, collection of information and documents before the assessment, post-audit feedback from auditees, etc.)	<input type="radio"/>	<input type="radio"/>
*Assessment strategies (e.g. record reviews, interviews to professional staff and patients, direct observation, etc.)	<input type="radio"/>	<input type="radio"/>
*Post-assessment procedures (e.g. on-site feedback to senior management, evaluation and feedback from the auditees with regards to the assessors, reporting format and style, procedure for validating draft final report and award decision, appeals to awards decisions)	<input type="radio"/>	<input type="radio"/>
*Competences requirement of assessors/auditors and their maintenance over time.	<input type="radio"/>	<input type="radio"/>

* Please include your comments.

500 character(s) maximum

* Should other requirements be added?

- ☐ Yes
- ☐ No
- ☐ I do not wish to answer this question

Proposed requirements Please
add one requirement/ row

	Text
Requirement 1	
Requirement 2	
Requirement 3	
Requirement 4	
Requirement 5	
Requirement 6	
Requirement 7	
Requirement 8	
Requirement 9	
Requirement 10	
Requirement 11	
Requirement 12	
Requirement 13	
Requirement 14	
Requirement 15	

2b The breast cancer treatment pathway

*** Is the proposed breast cancer treatment pathway generally applicable in the context of your healthcare system?**

- ☐ Yes
- ☐ No
- ☐ I do not wish to answer this question

Please include your comments.

500 character(s) maximum

2c. Subprocesses

*** Are the subprocesses mentioned appropriate?**

- ☐ Yes
- ☐ No
- ☐ I do not wish to answer this question

Please include your comments.

500 character(s) maximum

*** Are more subprocesses needed?**

- ☐ Yes
- ☐ No
- ☐ I do not wish to answer this question

Proposed subprocesses

Please add one subprocess/ row

	Text
Subprocess 1	
Subprocess 2	
Subprocess 3	
Subprocess 4	
Subprocess 5	
Subprocess 6	
Subprocess 7	
Subprocess 8	
Subprocess 9	
Subprocess 10	
Subprocess 11	
Subprocess 12	
Subprocess 13	
Subprocess 14	
Subprocess 15	

3a Modules and approaches for certification

*** Is the modular approach applicable in the healthcare system in your country?**

- ☐ Yes
- ☐ No
- ☐ I do not wish to answer this question

Please include your comments.

500 character(s) maximum

*** Is at least one scenario applicable in your country?**

- ☐ Yes
- ☐ No
- ☐ I do not wish to answer this question

*** Which one of the scenarios fits best in your healthcare setting?**

- ☐ One module approach
- ☐ Two modules approach
- ☐ Three modules approach

General comments regarding the document

Please insert here comments related to the content of the document which were not addressed in the above questions.

500 character(s) maximum

Thank you for your feedback!

Annex 2

European Quality Assurance scheme for Breast Cancer Services Scope

Annex 2 is an extract of the scope of the European Quality Assurance scheme for Breast Cancer Services. It highlights in red the parts that have been modified accordingly to the suggestions received from the online call for feedback. The official scope document is published separately.

This document concerns the scope of the **European Quality Assurance scheme for Breast Cancer Services** – in short, the **European QA scheme**.

The Directorate-General for Health and Food Safety (DG SANTE) asked the European Commission's Joint Research Centre (JRC) to coordinate the European Commission Initiative on Breast Cancer (ECIBC). One objective of the ECIBC is to develop the European guidelines for breast cancer screening and diagnosis, while another is to develop the *European QA scheme*. This scheme will define a common set of quality and safety requirements for breast cancer services in Europe. It will cover all the relevant areas of healthcare provision for breast cancer and all breast cancer care procedures. It will define its requirements by considering evidence-based recommendations arising from high-quality guidelines, where possible, best professional practices and the relevant legislation. On completion, it will be piloted among participant services in Europe.

A Quality Assurance Scheme Development Group (QASDG) was established in 2015 following a call for expression of Interest¹ organised by DG SANTE to support the EC in developing the *European QA scheme*, under the JRC's technical and scientific coordination. European Cooperation for Accreditation (EA) will provide support for framing the *European QA scheme* within the European legislation for accreditation (Regulation (EC) No 765/2008)² in view of its piloting and implementation.

This document represents the QASDG's first output and is meant to describe: a) the interventions and services that will be covered by the *European QA scheme*; b) the quality dimensions that will be included; and c) how the scheme will be implemented in the European context, according to the European legislation for accreditation. **All stakeholders and individual citizens were invited to provide their feedback on the draft document. The current document presents the results following the integration of the comments received.** A second call for feedback will be launched once the *European QA scheme's* requirements are available, and thus in the final version of the scheme's manual. More information about the ECIBC is available on the initiative's website³.

1 http://ec.europa.eu/health/major_chronic_diseases/diseases/cancer/call_ecibc_en.htm

2 Regulation (EC) No 765/2008 for Accreditation and Market Surveillance
(<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:en:PDF>)

3 <http://ecibc.jrc.ec.europa.eu>

Box 4: Breast cancer service definition in the ECIBC

The operational definition of **breast cancer service** within the ECIBC is: ‘all healthcare services covering, in continuum, the full extent of breast cancer management, from screening to follow-up, and in some cases until the end-of-life care’.

1.2 How accreditation is applied to the *European QA scheme*

In order to achieve consistency in the accreditation of conformity assessment bodies, NABs use harmonised standards. Since the *European QA scheme* will cover many healthcare procedures, including testing and examination activities, two main harmonised standards have been chosen: ISO 15189:2012 (Medical laboratories – Requirements for quality and competence) for the testing activities and ISO/IEC 17065:2012 (Conformity assessment – Requirements for bodies certifying products, processes and services). Both standards will be directly used by the NABs: the first for accrediting testing activities (e.g. laboratories) associated to BCSs aiming to adhere to the *European QA scheme*, and the second for accrediting **certification bodies** (CBs) which certify that the BCS fulfils all the specific requirements within the scheme. ISO 15189:2012 will be used for testing activities. **Possible time and equivalence derogations will be covered within the scheme’s owner requirements during the discussion and the QASDG’s approval processes.** Figure 1 summarises how the *European QA scheme* will work.

Box 5: Definition of a ‘certification body’

“A certification body is by definition a legal entity or a defined part of a legal entity” (source: <http://ul.com/customer-resources/ul-certification-bodies/>)

1.3 Certification scheme requirements (scheme owner requirements)

‘Accreditation and certification requirements’ include all the specifications on ‘how’ the ‘service/process requirements’ will be audited and checked.

For the BCS activities falling **under ISO/IEC 17065:2012**, those specifications will include:

- Methodology for rating requirements (e.g. numeric, Likert scale, non-conformity, etc.), weighting (if any), aggregation rules, and threshold scores for each section;
- Audit and surveillance requirements (e.g. frequency of audit and composition of auditing team);
- Pre-assessment procedures (e.g. self-assessment, collection of information and documents before the assessment, post-audit feedback from auditees, etc.);
- Assessment strategies (e.g. record reviews, interviews with professional staff and patients, direct observation, etc.);
- Post-assessment procedures (e.g. on-site feedback to senior management, evaluation and feedback from the auditees with regard to the assessors, reporting format and style, procedure for validating draft final report and award decision, appeals against awards decisions);
- Competency requirements of assessors/auditors and their maintenance over time;
- If monitoring criteria for assessors is to be offered to NABs, the scheme owner will have to monitor the technical performance of the standards, the scoring system and feedback from the field (the clients and their customers – see Figure 2).

For testing activities that will be accredited under ISO 15189:2012 **or an equivalent standard**, the ‘how’ is already defined both in the standard and in the NABs’ policies.

The EC as scheme owner would encourage the inclusion of a trained patient representative in the audits of the *European QA scheme*. Furthermore, the feasibility of a JRC-based central database of certification/accreditation outcomes will be tested during the pilot run. In fact, as scheme owner the EC is planning to maintain a central register of certified

2. Services, interventions, diseases and care processes covered

2.1. Services, interventions and diseases

The *European QA scheme* applies to BCSs, as defined in Box 4: ‘all healthcare services covering, in continuum, the full extent of breast cancer management, from screening to follow-up, and in some cases until the end-of-life care’.

This includes:

- Primary prevention when the intervention is specifically targeted at breast cancer (e.g. physical activity recommendations), although primary prevention interventions in general may be included as ‘service/process requirements’ in one or more of the breast cancer procedures (e.g. smoking cessation or alcohol reduction counselling in early diagnosis or treatment settings).
- Prevention (hormonal prevention or prophylactic mastectomy), surveillance, diagnosis (including genetic testing), treatment, rehabilitation and palliative care of breast cancer in women at increased risk of breast cancer also fall within the scope of the scheme.
- Lesions pathologically defined as associated with ‘uncertain malignant potential’ (so-called B3 lesions) also come under the scope of the scheme.
- Other non-malignant breast diseases are covered by the scheme when implied in a differential diagnosis of cancer.

Male breast cancer and other male breast diseases, such as gynecomastia, do not fall under the scope of this scheme; its blueprint may be adapted to breast cancer in male subjects in the context of a future project following the pilot run for female breast cancer.

2.2. Breast cancer **care** pathway

To ensure that accreditation and certification requirements follow a patient/person-centred approach, requirements will be defined by taking into account the care pathway (see Box 7) for breast cancer (and its related processes and sub-processes).

Box 7: Definition of 'care pathway'

The **care** pathway describes the healthcare chain and interfaces across healthcare sectors by bundling and visualising the outcomes of the relevant healthcare processes involved and considering quality targets. In detail, the care pathway aims at:

- Presenting the intervention/processes for which quality should be assured in a structured way;
- Presenting the relevant healthcare sectors involved;
- Assigning the responsibilities of healthcare providers to healthcare processes;
- Identifying starting points for quality assurance;
- Identifying quality potential within the treatment pathway.

The **care pathway** visualises via a flow chart the pathway followed by a person. This flow chart includes specific services, end points, quality targets and quality potentials relevant to the specific subject of the quality assurance scheme and by considering the course of the disease as well as the various services involved. (source: AQUA-Institute: Allgemeine Methoden 2015).

While dealing with breast cancer, persons go through different processes of care. Thereby, a general **care** pathway can be identified that applies to 'typical cases' of breast cancer. These **care** pathways are meant to be interpreted as a guide for the definition of requirements, and are not an exhaustive definition of all the possible variations of a general pathway, due to different local organisational settings, or specific individual cases of breast care that, for one reason or another, need to follow a different pathway. Existing descriptions of **care** pathways, e.g. the Washington State BCCHP Breast Care Algorithm⁹, may support the description of the processes. The simplified general care pathway proposed for the *European QA scheme* is represented in Figure 3.

9 http://www.kingcounty.gov/healthservices/health/chronic/bchp/~/_media/health/publichealth/documents/bchp/AlgorithmBreastCare.ashx

```

graph LR
    S1[1 Screening] --> S2[2 Diagnosis]
    S2 --> S3[3 Treatment]
    S3 --> S4[4 Rehabilitation]
    S4 --> S5[5 Follow-up & survivorship care]
    S5 --> S6[6 Palliative care]
    S5 --> S7[Suspect recurrent disease]
    S7 --> S1
    S7 --> S2
    S7 --> S6
    S6 --> S1
    S6 --> S2
    S6 --> S7
  
```

The flowchart illustrates the cancer care pathway, starting with Screening (1) and progressing through Diagnosis (2), Treatment (3), Rehabilitation (4), Follow-up & survivorship care (5), and Palliative care (6). A feedback loop exists from Follow-up & survivorship care (5) to Suspect recurrent disease, which then leads back to Screening (1), Diagnosis (2), or Palliative care (6). Additionally, a feedback loop exists from Palliative care (6) back to Screening (1), Diagnosis (2), and Suspect recurrent disease.

- Screening
- Diagnosis
- Treatment¹⁰
- Rehabilitation
- Follow-up and survivorship care
- Palliative care¹¹

The connection with primary care (general practitioner) at the moment of referral for suspected cancer and for the management of the follow-up, where appropriate, should also be taken into account.

See WHO, 2002: <http://www.who.int/cancer/palliative/definition/en/> last accessed 02/2016 for definition

Table 1a: Examples of breast cancer care sub-processes and their mapping according to the processes in which they play a role: person's pathway

	PROCESSES					
	SCREENING	DIAGNOSIS	TREATMENT	REHABILITATION	FOLLOW-UP AND SURVIVORSHIP CARE	PALLIATIVE CARE
Sub-processes						
Breast imaging and guided imaging interventions	x	x	x		x	
Nuclear medicine		x	x		x	
Breast pathology (cytology, histology, prognostics, genomics)		x	x		x	
Genetic evaluation (risk assessment) and testing	Only for women with an increased risk	x	x		x	
Laboratory testing	x	x	x	x	x	x
Breast surgery		x	x			
Breast reconstructive surgery			x			
Medical oncology			x		x	x
Radiation oncology			x		x	x
Other medical treatments		x	x	x	x	x
Fertility preservation			x			
Complementary and integrative medicine ¹²		x	x	x	x	x
Breast care nursing (including research nursing, community-based nursing and district nursing)	x	x	x	x	x	x
Rehabilitation modules and interventions: physiotherapy, psychotherapy, sexual counselling, neuro-cognitive, physical exercise, nutrition		x	x	x	x	x
Symptom control	x	x	x	x	x	x
Supportive care			x	x	x	x
Psycho-oncology (including screening for distress)	x	x	x	x	x	x
Social service counselling	x	x	x	x	x	x
Reintegration (e.g. going back to work)			x			
Patient/person involvement-empowerment (e.g. communication of the diagnosis and treatment plan, patient information, patient navigation, shared decision-making)	x	x	x	x	x	x
Primary prevention and health promotion	x	x	x	x	x	x

Table 1b: Examples of breast cancer care sub-processes and their mapping according to processes in which they play a role: care system processes

	PROCESSES					
	SCREENING	DIAGNOSIS	TREATMENT	REHABILITATION	FOLLOW-UP AND SURVIVORSHIP CARE	PALLIATIVE CARE
Team collaboration (including: multidisciplinary meeting/tumour board; handover)	X	X	X	X	X	X
Governance	X	X	X	X	X	X
Quality assurance of equipment imaging and therapy devices	X	X	X	X	X	X
Information to the public/citizens	X	X	X	X	X	X
Data management (databases and registries)	Only for women with an increased risk	X	X	X	X	X
Staffing	X	X	X	X	X	X
Training/teaching for professional staff	X	X	X	X	X	X
Quality management	X	X	X	X	X	X
Quality improvement (e.g. audit) and innovation	X	X	X	X	X	X
Patient safety (e.g. medication management)	X	X	X	X	X	X
Communication provider/person	X	X	X	X	X	X
Research	X	X	X	X	X	X

4.5 Quality domains

In the *European QA scheme*, classification of requirements will be proposed according to the following domains:

- Clinical effectiveness¹⁸
- Facilities, resources and workforce
- Personal empowerment and experience
- Safety

The domains are derived from the three key quality domains identified in the Reflection Paper ‘Patient safety and quality of healthcare: actions at EU level’¹⁹ with the further inclusion of a domain for structures and workforce.

Several external cancer and breast cancer quality assessment schemes (4) consider research and training provided to other BCSs by reference centres as either separate domains, independent from the scheme’s other requirements, or as requirements associated with specific care processes/sub-processes. In other cases, they are considered as additional activities that should be performed by reference centres or high-complexity BCSs. Both research and training will be considered in the *European QA scheme*.

Furthermore, the inclusion of additional transversal items may also be discussed by the QASDG. Such items refer to concepts that can be adopted from other existing classifications for different aspects of quality in health care, such as efficiency, access, equity, appropriateness, timeliness, acceptability, satisfaction, health improvement and continuity of care (9). Cost-effectiveness is also an important dimension of service provision that should be taken into account in the *European QA scheme*.

18 The word ‘effectiveness’ has been added on the basis of the NICE Healthcare quality standards process guide; as in the *European QA scheme* Manual, safety and effectiveness aspects will be tackled in two separate domains. ‘Effectiveness’ is defined as the degree of achieving desirable outcomes, given the correct provision of evidence-based healthcare services to all who could benefit (but not to those who would not benefit). This may include related dimensions of appropriateness, competence and capability (source: Organisation for Economic Co-operation and Development).

19 http://ec.europa.eu/health/patient_safety/docs/ps_qc_cons2013_background_en.pdf

The PDCA (plan-do-check-act) Cycle shows that the essential elements for a quality improvement system are defined requirements, compliance assessment methods, and incentives and mechanisms to enable improvement. The *European QA scheme* will adopt this view and will therefore focus on quality improvement²⁰.

Finally, a synopsis of the *European QA scheme*, including the manual, indicators and reference documents, is given in Figure 7.

20 Ongoing response to quality assessment data about a service in ways that improve the processes by which services are provided to clients (source: ISQua).

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